RECORD AND BRIEFS

FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039 and 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC., ET AL., RESPONDENTS

AMGEN INC., ET AL., PETITIONERS

v.

SANDOZ, INC., RESPONDENT

On Writs of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR THE BIOSIMILARS COUNCIL AS AMICUS CURIAE SUPPORTING SANDOZ INC.

ELAINE HERRMANN BLAIS
ALEXANDRA LU
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210

WILLIAM M. JAY
Counsel of Record
JAIME A. SANTOS*
GOODWIN PROCTER LLP
901 New York Ave., N.W.
Washington, DC 20001
wjay@goodwinlaw.com
(202) 346-4000

Counsel for Amicus Curiae

February 17, 2017

TABLE OF CONTENTS

PAGE

INTEREST OF THE AMICUS CURIAE 1

SUMMARY OF ARGUMENT 3

ARGUMENT 7

I. The BPCIA Allows Competition For Branded Biologic Medicines After The Statutory 12-Year Exclusivity Period, And Nothing In The Statute Or Its Legislative History Supports An Extra 6-Month Exclusivity Period. 7

A. Congress Developed the BPCIA's Abbreviated Pathway To Address The Extraordinary Cost of Branded Biologic Therapies 8

B. The Legislative History Makes Clear That Sponsors Would Enjoy Exclusivity For 12 Years And 12 Years Only. 14

C. An Additional 180 Days of Market Exclusivity Would Cost The Public Billions And Dampen Incentives For Biosimilar Development. 17

II. The Purpose Of The 180-Day Notice Rule Is To Allow Patent Litigation To Precede Launch, Not To Make The Parties Wait For A "Fully-Crystallized Controversy" Before Litigation Begins. 20

A. Permitting Patent Litigation To Take Place Only When The Patent Controversy Is "Fully Crystallized" Is Inconsistent With The Statutory Structure And Would Be Nonsensical In Many Cases. 21

B. Precluding Notice and Phase II Litigation Before FDA Approval Would Deprive Biologics, Biosimilar Developers, And Investors Of Much-Needed Certainty. 24

III. Respondents' Concerns About "Surprise" Biosimilar Applications Or Launches Do Not Support Enforcing The BPCIA's Patent Dance Provisions With An Extratextual Automatic Injunction Or Adding Six Months Of Extra Exclusivity Period For All Biologics..... 27

A. Respondents' Proposed Injunctive Remedy For A Biosimilar Developer's Failure To Engage In The Patent Dance Is Not Necessary To Protect Against A Secret Filing Or Surprise Launch. 27

B. Post-Licensure Notice Is Not Necessary To Protect Against A Stealth Launch. 34

CONCLUSION 36

TABLE OF AUTHORITIES

Page(s)

Cases

3Com Corp. v. D-Link Sys., Inc.,
No. C 03-2177 VRW, 2007 WL 949599
(N.D. Cal. Mar. 27, 2007) 32

Amgen, Inc. v. Apotex Inc.,
827 F.3d 1052 (Fed. Cir. 2016)..... 21

FTC v. Actavis, Inc.,
133 S. Ct. 2223 (2013) 2

Hoffmann-La Roche Inc. v. Invamed Inc.,
213 F.3d 1359 (Fed. Cir. 2000)..... 32

Janssen Biotech, Inc. v. Celltrion Healthcare Co.,
__ F. Supp. 3d __, 2016 WL 5420566 (D.
Mass. Sept. 26, 2016) 26

Mut. Pharm. Co. v. Bartlett,
133 S. Ct. 2466 (2013) 2

Patlex Corp. v. Mossinghoff,
758 F.2d 594 (Fed. Cir. 1985)..... 25

SAP Aktiengesellschaft v. i2 Techs., Inc.,
250 F.R.D. 472 (N.D. Cal. 2008) 33

Statutes and Rule

Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 119 (2010) 1

Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 29

21 U.S.C. § 355(j)(5)(F)(ii) 17

35 U.S.C. § 271(e)(2) 33

35 U.S.C. § 271(e)(4)(A) 4

35 U.S.C. § 271(e)(4)(B) 22

35 U.S.C. § 271(e)(4)(D) 22

42 U.S.C. § 262(k)(7) 7

42 U.S.C. § 262(k)(7)(A)-(B) 6

42 U.S.C. § 262(*l*)(2) 6

42 U.S.C. § 262(*l*)(6) 4

42 U.S.C. § 262(*l*)(8) 4

42 U.S.C. § 262(*l*)(8)(A) 7

42 U.S.C. § 262(*l*)(9)(C) 33

42 U.S.C. § 262(m)(2)(A) 8

42 U.S.C. § 262(m)(3)(A) 8

42 U.S.C. § 282(i) 29

Fed. R. Civ. P. 11 31

Legislative Materials

155 Cong. Rec. S5636 (daily ed. May 7, 2009) 12

155 Cong. Rec. D677 (daily ed. June 10, 2009) 13

155 Cong. Rec. D684 (daily ed. June 11, 2009) 13

155 Cong. Rec. S6793 (daily ed. June 18, 2009) 12

155 Cong. Rec. S7180 (daily ed. July 7, 2009) 15

155 Cong. Rec. S8187 (daily ed. July 28, 2009) 15

155 Cong. Rec. H12914 (daily ed. Nov. 7, 2009) 12

155 Cong. Rec. S11465 (daily ed. Nov. 18, 2009) 15

Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce, 110th Cong. (2007) 8

Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary, 111th Cong. (2009) .....*passim*

Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce, 111th Cong. (2009)..... 12-13

Health Care Reform Roundtable (Part II): Hearing Before the S. Comm. on Health, Education, Labor & Pensions, 111th Cong. (2009) 14

H.R. Rep. No. 96-1307 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460 25

Pathway for Biosimilars Act, H.R. 1548, 11th Cong. § 101 (2009)..... 22

Other Authorities

Norman L. Balmer, *An Innovator's Prospective on Judicial Management in the United States*, 9 Fed. Cir. B.J. 615 (2000) 25

Biosimilars Council, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products* (2015), *available at* http://www.biosimilarscouncil.org/pdf/GPhA-biosimilars-handbook.pdf..... 2

Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, Am. Health & Drug Benefits 469 (2013)..... 8, 18, 35

Cadila Healthcare Limited, *Investor Presentation* (May 2016), https://zydus cadila.com/wp-content/uploads/2016/ 05/InvestorPresentation-May2016.pdf 30

Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671 (2010) 14

Coherus Biosciences, Press Release, Coherus Biosciences Announces Positive Topline 24-Week Treatment Phase Three Results For CHS-1420 (Humira® Biosimilar Candidate) In Patients With Psoriasis (Jan. 10, 2017), http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2236538 30

Cong. Budget Office, *Cost Estimate, S. 1695, Biologics Price Competition and Innovation Act of 2007* (June 25, 2008), *available at* https://www.cbo.gov/sites/ default/files/110th-congress-2007-2008/costestimate/s16950.pdf 10, 11, 18

Alfred B. Engelberg et al., *Balancing Innovation, Access, and Profits—Market Exclusivity for Biologics*, 361 N. Engl. J. Med. 1917, 1919 (2009) 14

Eshoo-Barton Biosimilars Bill Drops Unintended Botox Protection, FDA Week, Mar. 13, 2009, 2009 WLNR 4803584 16

Express Scripts, Inc., *The $250 Billion Potential of Biosimilars* (Apr. 23, 2013), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars 18

Fed. Judicial Ctr., *Patent Case Mgmt. Judicial Guide* (2009) 32

Fed. Trade Comm'n, *Emerging Health Care Issues: Follow-On Biologic Drug Competition* (June 2009), *available at* http://bit.ly/2e5Wy2m 13, 14, 19, 20, 26

Food & Drug Admin., Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017, *available at* http://bit.ly/2ecO0Yw 6, 34

Food & Drug Admin., Press Release, FDA Approves First Biosimilar Product Zarxio (Mar. 6, 2015), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm 34

Donna M. Gitter, *Biopharmaceuticals Under the Patient Protection and Affordable Care Act: Determining the Appropriate Market and Data Exclusivity Periods*, 21 Tex. Intell. Prop. L.J. 213, 229 (2013) 17

HELP Approves Biosimilars Provision with 12 Years of Exclusivity, FDA Week, July 17, 2009, 2009 WLNR 13664255 15

IMS Institute for Healthcare Informatics, *Delivering on the Potential of Biosimilar Medicines* (Mar. 2016), *available at* http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf 6

Judith A. Johnson, Cong. Research Serv., *Biologics and Biosimilars: Background and Key Issues* (Sept. 7, 2016), *available at* https://fas.org/sgp/crs/misc/R44620.pdf..... 9, 10

Judith A. Johnson, Cong. Research Serv., *FDA Regulation of Follow-On Biologics* (Apr. 26, 2010), *available at* http://bit.ly/2dTKKoX 9, 14

Erika Lietzan, *The Myths of Data Exclusivity*, 20 Lewis & Clark L. Rev. 91 (2016)..... 22

Makers of Plasma Protein Therapies Support Eshoo's Biosimilars Bill, FDA Week, July 10, 2009, 2009 WLNR 13169335..... 15

Andrew W. Mulcahy et al., Rand Corporation, *The Cost Savings Potential of Biosimilar Drugs in the United States* (2014), *available at* https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf 18-19

Bernard Munos, *2015 New Drug Approvals Hit 66-Year High!*, Forbes.com (Jan. 4, 2016), http://www.forbes.com/sites/bernardmunos/2016/01/04/2015-new-drug-approvals-hit-66-year-high/#4ecaa3c11044 1-2

Nat'l Institutes of Health, *History, Policies, and Laws*, ClinicalTrials.gov (Feb. 2, 2017), https://clinicaltrials.gov/ct2/about-site/history#CongressPassesLawFDAMA 29

Nine Energy & Commerce Dems Urge Waxman to Mark Up Biosimilars Bill, FDA Week, June 19, 2009, 2009 WLNR 11765201. 15

Office of Mgmt. & Budget, *A New Era of Responsibility* 28 (2009), *available at* http://www.washingtonpost.com/wp-srv/politics/budget2010/fy10-newera.pdf..... 11-12

Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending 2, 10-11

W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 Iowa L. Rev. 1023 (2016) 9, 18, 19

Sandoz, *Meet Novartis Management Investor Presentation* (May 2016), https://www.novartis.com/sites/www.novartis.com/files/2016-06-meet-the-management-3-sandoz.pdf 30

Sandoz, Press Release, FDA accepts Sandoz application biosimilar filgrastim (Jul. 24, 2014), https://www.sandoz.com/news/media-releases/fda-accepts-sandoz-application-biosimilar-filgrastim 30

Sandoz, Press Release, FDA approves Sandoz Erelzi™ to treat multiple inflammatory diseases (Aug. 30, 2016), https://www.sandoz.com/news/media-releases/fda-approves-sandoz-erelzitm-treat-multiple-inflammatory-diseases 34-35

Senate Democrats' Biosimilars Deal Falls Apart in Meeting, FDA Week, July 10, 2009, 2009 WLNR 13169315 16

Surya C. Singh & Karen M. Bagnato, *The Economic Implications of Biosimilars*, Am. J. Managed Care S331 (2015) 10, 18, 29, 20

John R. Thomas, Cong. Research Serv., *Follow-On Biologics: The Law and Intellectual Property Issues* (Jan. 15, 2014), *available at* https://www.fas.org/sgp/crs/misc/R41483.pdf 10, 18, 20

U.S. Gov't Accountability Office, *Report to the Ranking Member, Committee on the Budget, House of Representatives* (Oct. 2015)..... 7, 9, 10, 11

BRIEF FOR THE BIOSIMILARS COUNCIL AS AMICUS CURIAE SUPPORTING SANDOZ INC.

INTEREST OF THE AMICUS CURIAE

The Biosimilars Council (the "Council"), a division of the Association for Accessible Medicines ("AAM"), represents the companies and stakeholder organizations working to develop biosimilar products for the U.S. pharmaceutical market.[1] Biosimilars are highly similar or interchangeable versions of branded biologic medicines licensed by the Food and Drug Administration ("FDA"), and an entity seeking FDA approval of a biosimilar is known as a biosimilar "applicant." A branded biologic in this context is known as a "reference product" and its license holder as the reference product "sponsor." Congress established an expedited FDA approval pathway for biosimilars in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA").[2]

The Council's members aim to provide consumers with access to safe, effective alternatives to expensive biologic therapies. Biologic medicines now account for nearly 40% of annual drug approvals by the FDA. Bernard Munos, *2015 New Drug Approvals Hit 66-Year High!*, Forbes.com (Jan. 4, 2016),

---

[1] The parties consented to the filing of this brief. No counsel for a party authored any part of this brief; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

[2] Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 119 (2010).

http://www.forbes.com/sites/bernardmunos/2016/01/04/2015-new-drug-approvals-hit-66-year-high/#4ecaa3c11044. With annual U.S. spending on biologic drug therapies in the United States exceeding $100 billion,[3] and only a few biosimilars available on the U.S. market thus far, biosimilars offer the potential for tens of billions of dollars in health savings. And savings are not limited to consumers and private insurers: the federal government spends more than $5 billion each year on biologic drug therapies through such programs as Medicare and Medicaid.[4]

The Council and its members supported passage of the BPCIA and are deeply interested in its correct implementation and interpretation. To that end, the Council has participated in litigation as *amicus curiae* regarding the proper interpretation of the BPCIA, taking legal positions that reflect the position of the Council as an organization. The Council filed a brief in this case below and in support of Sandoz's petition for certiorari. The Council's parent organization, formerly named the Generic Pharmaceutical Association, has likewise frequently participated in litigation as *amicus curiae* regarding patent and regulatory issues affecting pharmaceutical manufacturers. *See, e.g., Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

---

[3] *See* The Biosimilars Council, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products* 14 (2015), *available at* http://www.biosimilarscouncil.org/pdf/GPhA-biosimilars-handbook.pdf.

[4] Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending.

The Council's members have all sought or intend to seek FDA approval of biosimilar products through the BPCIA's abbreviated approval pathway. They are and will continue to be subject to the complex set of rules that govern approval and related patent litigation with biologic manufacturers. The Council and its members therefore have a strong interest in ensuring that the BPCIA is interpreted in a manner consistent with Congress's goal of expediting patient access to affordable versions of biologic therapies. That principle requires two conclusions here: *First*, the Federal Circuit was wrong to give biologic manufacturers an additional six months' market exclusivity beyond the already-generous twelve years the BPCIA expressly provides. *Second*, the Federal Circuit was right to hold that when a biosimilar applicant decides not to provide its confidential information to a biologic sponsor, the sponsor's sole remedy is the one set out in the statute: a patent-infringement action.

SUMMARY OF ARGUMENT

The BPCIA is a complex statute that was drafted over several years with extensive input from numerous federal agencies, legislators, and industry representatives. When Congress provided a 12-year exclusivity period in that statute, it meant 12 years, not 12½; when Congress omitted an injunctive remedy, its omission was no accident.

The BPCIA attempts to spur investment in cost-saving biosimilar products by creating a new abbreviated pathway for biosimilar approval—but only after the biologic product enjoys a 12-year period of exclusivity protection against biosimilar competition,

the longest such period in the world. Congress recognizes that marketing a biosimilar will sometimes raise patent issues, and it sought to lower the temperature of such patent litigation by creating a procedure to simplify it. The BPCIA creates strong incentives for biosimilar applicants to provide confidential, proprietary business information to sponsors voluntarily. That information exchange—known as the "patent dance"—can allow patent disputes to be resolved without the need to overwhelm courts with the kitchen-sink approach to litigation.

The BPCIA allows the parties to choose a two-phase process for patent litigation over a biosimilar: Phase I, limited to the patent issues that the parties decide to litigate shortly after a biosimilar application is filed, 42 U.S.C. § 262(*l*)(6), and Phase II, involving any remaining patents, *id.* § 262(*l*)(8). The BPCIA does not tie FDA approval to the resolution of patent disputes, as does the statute governing approval of generic small-molecule drugs ("Hatch-Waxman"), *see* 35 U.S.C. § 271(e)(4)(A). Rather, the BPCIA allows the parties to choose to sequence their patent dispute by providing different triggers for the litigation of Phase I and Phase II patents. But if the applicant chooses not to opt in to the patent dance, the statute permits immediate litigation of all patents. *See* Sandoz Br. 12-13.

Apparently unsatisfied with the provisions in the statute itself, respondents[5] seek rights and remedies that are nowhere to be found in the text of the BPCIA. First, respondents seek an additional 180-

---

[5] "Petitioner" and "respondents" refer to the parties in the lead case, No. 15-1039.

day exclusivity period *in every case*: they contend that the applicant's advance notice of commercial marketing required by the statute cannot be effective until after biosimilar products receive FDA approval, so the applicant must *always* wait 180 days after approval before marketing. Second, they argue that the consequence for an applicant's failure to engage in the patent dance is not limited to the remedies set forth in the BPCIA itself (the sponsor's entitlement to file a patent-infringement action), but instead also includes the right to an automatic injunction ordering applicants to provide their confidential business information to sponsors. These claims find no support in the statute itself or its legislative history.

The BPCIA's multi-year history makes clear that, in light of the needed cost-saving benefits of abbreviated approval for biosimilars, Congress gave sponsors a period of exclusivity that is 12 years and 12 years only, extendable only based on pediatric research. Proponents and critics alike recognized that the period is 12 years in all cases; *no one* referred to the period as 12½ years, as respondents would have it.

Respondents base their interpretation not on the text or history, but on various inferences about how patent litigation ought to proceed. But those inferences are unfounded. Respondents have argued that notice of commercial marketing cannot be provided until after FDA approval to ensure that the second phase of patent litigation does not occur until after the FDA defines the right and scope of biosimilar manufacture and sale. But if Congress wanted to delay litigation until after final FDA licensure, it would not have created an early patent-resolution process

that begins just "20 days" after a biosimilar application is accepted for filing, 42 U.S.C. § 262(*l*)(2), which can occur *eight years* before licensure, *id.* § 262(k)(7)(A)-(B). Respondents have also argued that their interpretations of both the patent-dance and notice provisions are necessary to prevent "surprise" launches by biosimilar manufacturers, but this concern is simply baseless given the transparency of the biosimilar pipeline[6] and the FDA's clear communications regarding its biosimilar approval timeline.[7]

Properly interpreted, the BPCIA will spur investments in biosimilars and provide financial relief to consumers, insurers, and federal and state governments, which currently pay more than $100 billion per year for biologics. In contrast, respondents' interpretation upsets the careful balance struck by Congress between encouraging future investment in biosimilar production and protecting the investments made by biologic companies. Moreover, respondents' interpretation needlessly delays much-needed financial relief that biosimilar products offer. And with many biologics costing more than $50,000 *per year*

---

[6] *See, e.g.*, IMS Institute for Healthcare Informatics, *Delivering on the Potential of Biosimilar Medicines* 11 (Mar. 2016), *available at* http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf (discussing the 41 biosimilars in the pipeline as of March 2016).

[7] *See* FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017, at 3-4 (FDA Biosimilar Authorization Performance Goals), *available at* http://bit.ly/2ecO0Yw.

per patient to treat serious illnesses, this relief cannot come fast enough.[8]

ARGUMENT

I. THE BPCIA ALLOWS COMPETITION FOR BRANDED BIOLOGIC MEDICINES AFTER THE STATUTORY 12-YEAR EXCLUSIVITY PERIOD, AND NOTHING IN THE STATUTE OR ITS LEGISLATIVE HISTORY SUPPORTS AN EXTRA 6-MONTH EXCLUSIVITY PERIOD.

The BPCIA requires biosimilar applicants to "provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The text cannot reasonably be read to restrict applicants from providing such notice before FDA approval. That reading would necessarily extend the biologic's market-exclusivity period to 12½ years in every instance, as respondents' counsel expressly told the district court.[9] But the BPCIA is quite clear on the market exclusivity enjoyed by sponsors: it states that the "[e]xclusivity for reference product" is "12 years." *Id.* § 262(k)(7). And in the one instance in which Congress wanted to extend this exclusivity beyond

---

[8] U.S. Gov't Accountability Office, Report to the Ranking Member, Committee on the Budget, House of Representatives 19 Tbl. 4 (Oct. 2015), http://www.gao.gov/assets/680/673304.pdf.

[9] Tr. of Mot. Hrg. at 65, No. C 14-4741 RS, ECF No. 104 (N.D. Cal. Mar. 17, 2015) (PI Mot. Hrg.) ("**THE COURT**: . . . Is there any scenario under your reading of [the BPCIA] that would allow anyone, any subsection (k) applicant, to go to market in less than 12 1/2 years? **[AMGEN'S COUNSEL]**: There is not.").

the 12-year mark, it did so expressly, providing that when sponsors conduct pediatric studies at the Secretary's request, the exclusivity period is "deemed to be . . . 12 years and 6 months rather than 12 years." 42 U.S.C. § 262(m)(2)(A), (3)(A). Respondents attempt to rewrite the statute to allow *every* sponsor to enjoy "12 years and 6 months rather than 12 years" of exclusivity, arguing that Congress "intended the notice of commercial marketing and its 180-day period to follow FDA approval." Amgen Br. in Opp. 20. But the statute's text, structure, and legislative history provide no support for this proposition, which would undermine the access to lower-cost biologic therapies that the BPCIA was enacted to promote.

A. Congress Developed the BPCIA's Abbreviated Pathway To Address The Extraordinary Cost of Branded Biologic Therapies.

Biologic drugs offer incredible promise in providing life-saving therapies for some of the most difficult-to-treat illnesses (such as cancer, genetic diseases, and blood disorders), but to date they have come at extraordinary cost. As Congress was informed in 2007, the average daily cost of a biologic ($45) was more than 22 times the average daily cost of a traditional pharmaceutical ($2). *See Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 125-128 (2007) (statement of Ed Weisbart, M.D., Chief Medical Officer, Express Scripts, Inc.); *accord* Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 469 (2013). For that

reason, Congress was highly motivated in the BPCIA to create a pathway that would avoid unnecessary delay or uncertainty in bringing biosimilars to market.

Many biologics cost tens of thousands of dollars annually *per patient*. Congress was aware when it adopted the BPCIA that Herceptin®, used to treat breast cancer, cost $37,000 per patient annually, and Cerezyme® cost $200,000 per patient annually to treat Gaucher's disease. *See* Judith A. Johnson, Cong. Research Serv., *FDA Regulation of Follow-On Biologics* 1 (Apr. 26, 2010) (CRS 2010), *available at* http://bit.ly/2dTKKoX. That trend continues: several biologics covered by Medicare Part B cost the government more than $50,000 per beneficiary per year, and at least one costs the government nearly *half a million* dollars annually per beneficiary. U.S. Gov't Accountability Office, *Report to the Ranking Member, Committee on the Budget, House of Representatives* 19 Tbl. 4 (Oct. 2015) (GAO Report), *available at* http://www.gao.gov/assets/680/673304.pdf; *see also* Judith A. Johnson, Cong. Research Serv., *Biologics and Biosimilars: Background and Key Issues* 2 (Sept. 7, 2016) (CRS 2016), *available at* https://fas.org/sgp/crs/misc/R44620.pdf (both Soliri® and Vimizim® exceed $250,000 per patient annually).

Biologics prices have had a profound impact on overall healthcare costs. "Spending on small-molecule drugs is close to stagnant," W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 Iowa L. Rev. 1023, 1026 (2016), but U.S. spending on biologics has more than doubled in the past ten years, from about $40 billion in 2006 to $92 billion in 2013—a whop-

ping 28% of all U.S. drug spending even though the number of approved small-molecule drugs dwarfs the number of approved biologics, *see* Cong. Budget Office, *Cost Estimate, S. 1695, Biologics Price Competition and Innovation Act of 2007*, at 5 (June 25, 2008) (CBO, *Cost Estimate*), *available at* https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf; CRS 2016, at 2-3. Indeed, annual spending on biologics has grown by 10-20% each year, whereas spending on traditional pharmaceuticals has remained almost level and spending on hospital and physician services has increased only by single digits. *See id.* at 5; CRS 2016, at 2-3; John R. Thomas, Cong. Research Serv., *Follow-On Biologics: The Law and Intellectual Property Issues* 2 (Jan. 15, 2014) (CRS 2014), *available at* https://www.fas.org/sgp/crs/misc/R41483.pdf.

This impact is not limited to consumers or private insurers: Medicare has also experienced massive spending increases on biologics in recent years. Spending on biologics under Part D grew from $1.9 billion to $3.5 billion between 2009 and 2012. Surya C. Singh & Karen M. Bagnato, *The Economic Implications of Biosimilars*, 21 Am. J. Managed Care S331, S331 (2015). In 2013 just *three* new biologics were alone responsible for more than half of the $5.9 billion that Medicare and Medicare beneficiaries spent on new Part B drugs and for 15% of *all* spending on Part B drugs that year ($20.9 billion). GAO Report 15-16.[10] By 2014, Part B spending on just five biologics totaled nearly $5.5 billion. Pew Chari-

[10] Medicare Part B covers drugs administered by physicians, typically in a clinic, doctor's office, or outpatient facilities; Part D covers self-administered outpatient prescription drugs.

table Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending. The enormous costs of biologics are putting a drastic financial burden on federal insurance programs and their beneficiaries.[11]

These cost concerns are precisely what animated Congress to pass the BPCIA, with legislators and commentators from across the political spectrum acknowledging the need for an abbreviated approval pathway to bring relief to patients, insurers, and government insurance programs and to address the healthcare cost crisis. Congress sought to quantify the cost savings that could result from an abbreviated approval pathway for biosimilars (then-named "follow-on biologics") as early as 2007. *See* CBO, *Cost Estimate* 1-9.

Later, when the BPCIA and predecessor legislation were being debated, the President and Congress discussed the urgent financial need for an abbreviated biosimilar approval pathway. In its proposed budget released in February 2009, the Obama Administration noted that "[p]rescription drug costs are high and rising" and proposed "accelerate[d] access" with a "legal pathway for generic versions of biologic drugs." Office of Mgmt. & Budget, *A New Era of Re-*

---

[11] Part B beneficiaries are required to pay 20% of their drugs' costs, totaling thousands (sometimes tens of thousands) of dollars each year for many beneficiaries who rely upon biologic drugs. GAO Report 18 (332,000 beneficiaries had cost-sharing responsibilities ranging between $1,900 and $107,000 in 2013). Yet the average Medicare beneficiary's annual income is just $23,500. *Id.*

sponsibility 28 (2009), *available at* http://www.washingtonpost.com/wp-srv/politics/budget2010/fy10-neweera.pdf. A diverse group of legislators likewise addressed the need for lower-cost options for biologic therapies. *See, e.g.*, 155 Cong. Rec. H12914 (daily ed. Nov. 7, 2009) (statement of Rep. Shuler) (discussing the "moral obligation to provide a safe and effective pathway of bringing competition that will benefit patients"); 155 Cong. Rec. S6793 (daily ed. June 18, 2009) (statement of Sen. Brown) ("Perhaps nowhere [is the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics. . . . With costs to biologics ranging anywhere from $10,000 to $200,000 per patient per year, biologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments that are also paying the bills."); *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 7 (2009) (*Biologics and Biosimilars Hearing*) (statement of Rep. Eshoo) (noting the "vital future" in the field of biotechnology but noting that given the "very expensive" "cost of biologic treatments . . . the time has come to develop a pathway . . . for biosimilar products"); 155 Cong. Rec. S5636 (daily ed. May 7, 2009) (statement of Sen. Clinton) ("follow-on biologics" pathway necessary to "provide significant savings to patients, employers, and the government" on the order of "$14 billion over the next 10 years"); *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H.*

Comm. on Energy & Commerce, 111th Cong. 2 (2009) (statement of Rep. Pallone) ("If biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like Hatch-Waxman did.").

Reports submitted to Congress by the Federal Trade Commission ("FTC") and CBO and considered at congressional hearings[12] confirmed the cost savings that Congress's proposed abbreviated pathway could bring. The CBO estimated $25 billion in cost savings over a ten-year period, including more than $6 billion in direct government expenditures through Medicare, Medicaid, and other programs. CBO, *Cost Estimate* 5. The FTC estimated biosimilar price discounts of 10 to 30 percent, noting that "[a]lthough not as steep a discount as small-molecule generic drugs, a 10 to 30 percent discount on a $48,000 drug product represents substantial consumer savings." FTC, *Emerging Health Care Issues: Follow-On Biologic Drug Competition*, at v (June 2009) (FTC, *Follow-on Biologic Drug Competition*), *available at* http://bit.ly/2e5Wy2m.

The same theme recurs throughout the legislative history: the urgent need to access the cost savings that biosimilars could bring was the key motivation for adopting the BPCIA in 2010.

---

[12] *See, e.g.*, 155 Cong. Rec. D684 (daily ed. June 11, 2009); 155 Cong. Rec. D677 (daily ed. June 10, 2009).

B. The Legislative History Makes Clear That Sponsors Would Enjoy Exclusivity For 12 Years And 12 Years Only.

The longer the exclusivity period granted to biologic sponsors, the longer before consumers, insurers, and the government could access the much-needed savings offered by a biosimilar pathway. The duration of that exclusivity period therefore was critically important. The statute ultimately set the period at "12 years," not 12½.

The 12-year period was a hard-fought compromise. The Obama Administration proposed a seven-year exclusivity period.[13] Others suggested an even shorter five-year period.[14] Branded biologics industry groups, in contrast, advocated for a much longer 14-year period.[15] But the FTC warned that such a lengthy period was unnecessary to promote innovation.[16] Eventually, Congress adopted a 12-year exclusivity period, to run from the date of the biologic's licensure, irrespective of any patents.

When that 12-year period was being debated, not a single legislator or stakeholder was under the impression that every biosimilar would enjoy 12½ years of market exclusivity. Instead, opponents decried the "12-year" period as unfair, unnecessary, and un-

---

[13] CRS 2010, at 3-4.

[14] *See, e.g.*, Alfred B. Engelberg et al., *Balancing Innovation, Access, and Profits—Market Exclusivity for Biologics*, 361 N. Engl. J. Med. 1917, 1919 (2009).

[15] Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 726-27, 735-36, 772 (2010).

[16] *See* FTC, *Follow-on Biologic Drug Competition* 25-46.

just,[17] while supporters applauded the "12-year" period.[18] Indeed, Representative Eshoo, whose proposed amendment containing a biosimilar pathway

---

[17] *See, e.g.*, 155 Cong. Rec. S8187 (daily ed. July 28, 2009) (statement of Sen. Brown) ("Let's hope that we in Congress take a stand for fiscal responsibility, for common sense, and for the Americans we serve by ratcheting down the 12-year monopoly sweetheart deal that the big drug companies are peddling"); *Health Care Reform Roundtable (Part II): Hearing Before the S. Comm. on Health, Education, Labor & Pensions*, 111th Cong. 35 (2009) (statement of John Rother, Executive Vice President for Policy & Strategy, AARP) ("[W]e continue to have concerns—also echoed in the FTC report about the 12-year exclusivity period included in the Senate HELP Committee compromise."); 155 Cong. Rec. S7180 (daily ed. July 7, 2009) (statement of Sen. Brown) ("[I]t takes less than 2 years for the average brand-name biologic to recoup the R&D cost. Why are some of my colleagues advocating for a 12-year monopoly period?"); 155 Cong. Rec. S11465 (daily ed. Nov. 18, 2009) (statement of Sen. Sanders) (noting the need to "stop drug companies from having exclusivity for 12 years").

[18] *See, e.g.*, *Biologics and Biosimilars Hearing* 184-188 (statement of Jack W. Lasersohn, General Partner, Verticle Group) (arguing that "12 years" of exclusivity is necessary to "protect biologics pioneers," and the "seven-year" period advocated by others would provide insufficient protection); *HELP Approves Biosimilars Provision with 12 Years of Exclusivity*, FDA Week, July 17, 2009, 2009 WLNR 13664255 (biological industry organization praised the "12-year proposal," saying that "[w]ith this vote, the HELP Committee has embraced our long held belief that a minimum of 12 years of data exclusivity establishes a fair and reasonable period to ensure continued biomedical innovation and provide the benefits of competition"); *Makers of Plasma Protein Therapies Support Eshoo's Biosimilars Bill*, FDA Week, July 10, 2009, 2009 WLNR 13169335 (industry organization supporting "a brand biologics-friendly bill" referenced the exclusivity period "of 12 years from the date of first licensure" as the "best" way to protect patient access and innovator resources).

with a 12-year exclusivity provision was eventually incorporated into the House version of the BPCIA, said that "innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics." *Biologics and Biosimilars Hearing* 8.

The myriad references to a "12-year" exclusivity period were not merely a matter of rounding down. When earlier proposals included, for example, 14½ years of exclusivity for sponsors, coverage of the legislative developments characterized the period accordingly.[19] Likewise, when there was uncertainty about the exclusivity period offered under any particular proposal, those disputes were ventilated during the legislative process. *See, e.g.*, *Senate Democrats' Biosimilars Deal Falls Apart in Meeting*, FDA Week, July 10, 2009, 2009 WLNR 13169315 (discussing disagreement about whether a proposed bill provided 9 years or 12 years of exclusivity). But there was no disagreement about the exclusivity offered by the legislation that was eventually passed—respondents have not pointed to (and the Council has not found) a single mention of the BPCIA offering

---

[19] *E.g.*, *Eshoo-Barton Biosimilars Bill Drops Unintended Botox Protection*, FDA Week, Mar. 13, 2009, 2009 WLNR 4803584 ("The upcoming bill, with its expected 14 1/2 years of market exclusivity for brand biologics, will offer a brand-friendly alternative to legislation introduced Wednesday (March 11) by committee Chair Henry Waxman (D-CA)."); *Nine Energy & Commerce Dems Urge Waxman to Mark Up Biosimilars Bill*, FDA Week, June 19, 2009, 2009 WLNR 11765201 ("Waxman's bill calls for up to five years of exclusivity for brand biologics, but the alternative bill, sponsored by Rep. Anna Eshoo (D-CA), calls for 14 1/2 years of exclusivity.").

12½ years of exclusivity before a biosimilar could begin marketing its approved product. This issue would not have gone unnoticed. If industry groups or legislators believed the BPCIA offered 12½ years, pro-biologics groups would have been trumpeting this victory, and pro-biosimilars groups and legislators would have been criticizing this compromise, just as both did regarding the "12-year" period that all interested parties understood the statute to provide. The lack of any mention, whatsoever, of a 12½-year exclusivity period in the legislative history or contemporaneous press reports is irreconcilable with the notion of a 12½-year period that applies in every case, as respondents seek.

C. An Additional 180 Days of Market Exclusivity Would Cost The Public Billions And Dampen Incentives For Biosimilar Development.

1. The BPCIA's 12-year exclusivity period is lengthy to begin with. It exceeds the biologic exclusivity period available in every other country that has created an abbreviated biosimilar pathway. Europe has the second-longest exclusivity period, generally providing for ten years of market exclusivity; Canada's biologic exclusivity period is eight years. Donna M. Gitter, *Biopharmaceuticals Under the Patient Protection and Affordable Care Act: Determining the Appropriate Market and Data Exclusivity Periods*, 21 Tex. Intell. Prop. L.J. 213, 229 (2013). Other countries (including Australia, New Zealand, Japan, and South Korea) permit just five or six years of market exclusivity for biologics. *Id.* at 231. In addition, the BPCIA's 12-year period is more than double the exclusivity period available for entirely new

small-molecule drugs under the Hatch-Waxman Amendments. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (five-year exclusivity for new chemical entities). The Federal Circuit's categorical rule thus makes the BPCIA's more-than-generous exclusivity provision even longer, and brings the United States even more out of step with the rest of the world.

There is a reason why every other country on the planet provides a shorter exclusivity period than the United States: biosimilars offer potential savings of billions of dollars per year. As noted above, the astronomical costs of biologic products are placing extraordinary burdens on consumers, private insurers, and government programs. Biosimilars in Europe, which have developed for years under abbreviated approval pathways, are generally priced 15-30% lower than reference biologic products. Blackstone & Fuhr 24; Price & Rai 1028. Experts and commentators have estimated that near-term discounts in the United States will likely be between 10-35%, and brand biologics may likewise cut their prices to discourage patients from switching to biosimilars. *Id.* at 27; Singh & Bagnato 19; CRS 2014, at 17-18 (collecting estimates).

Given the high price of biologic therapies, near-term discounts of even 15-30% over a six-month period offer significant cost savings. Ten-year savings created by the BPCIA are estimated to be at least $25 billion and potentially as high as $250 billion.[20]

---

[20] *See, e.g.*, CBO Estimate 5; Express Scripts, Inc., *The $250 Billion Potential of Biosimilars* (Apr. 23, 2013), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars; *see also* Andrew W. Mulcahy et al., Rand Corporation, *The Cost Savings Potential of Biosimilar*

If every biologic is assured an extra six months of exclusivity, that shifts literally billions of dollars from patients, federal programs, and insurance premiums to biologic sponsors. For an individual Medicare Part B beneficiary responsible for thousands of dollars per year in cost-sharing payments for a biologic drug that costs $50,000 or even $200,000 per year, or for a patient with private insurance and similar cost-sharing obligations, the six-month savings could mean the difference between selecting and forgoing much-needed therapies for serious illnesses.

2. The Federal Circuit's rule would be at least as detrimental for biosimilar manufacturers and potential biosimilar manufacturers as it would be for consumers, insurers, and taxpayers. Developing and manufacturing biosimilars is particularly expensive and time-consuming—far beyond the cost and time to develop and manufacture generic small-molecule drugs. As the FTC reported in 2009, development of each biosimilar will cost between $100 million and $200 million and take between eight and ten years, in comparison with small-molecule generic drugs, "which typically take three to five years to develop and cost between $1 and $5 million." FTC, *Follow-On Biologic Drug Competition*, at iii.[21] These cost

---

Drugs in the United States 7 (2014) ($44.2 billion), *available at* https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

[21] *See also* Price & Rai 1028 (European biosimilar manufacturers "have on average expended between $100 million and $250 million and seven to eight years in the reverse engineering necessary to bring these products to market," and the cost "is likely to rise" as harder-to-manufacture biologics "begin to dominate the market"); Singh & Bagnato S333 ("The average cost of clinical development for a biosimilar ranges from $40 million to $300 million, and development takes up to 5 years . . . .").

and time commitments are on top of the $250 million to $1 billion investment that is required for drug companies "to build, equip and qualify their own manufacturing facilities," *id.* at 14, which the FDA takes about four years to approve, *see* CRS 2014, at 15; *see also id.* ("In addition, the cost of materials to manufacture biologics may be 20 to 100 times more than chemical drugs.").

The extra six months of market exclusivity created by the Federal Circuit's rule might not, upon initial glance, seem significant. But for a company that has spent or is considering spending half a billion dollars to build an appropriate manufacturing facility and successfully develop a biosimilar, the need to recoup that investment is very real. As the FTC has observed, given the high costs of entering the biosimilars market, the number of potential entrants is limited. FTC, *Follow-On Biologic Drug Competition* 14-15. The Federal Circuit's creation of an additional six-month delay before these companies can begin to recover their substantial investments is likely to shrink the universe of potential candidates still further.

II. THE PURPOSE OF THE 180-DAY NOTICE RULE IS TO ALLOW PATENT LITIGATION TO PRECEDE LAUNCH, NOT TO MAKE THE PARTIES WAIT FOR A "FULLY-CRYSTALLIZED CONTROVERSY" BEFORE LITIGATION BEGINS.

The Federal Circuit justified its post-licensure rule based on its "belie[f]" that Congress intended the notice to follow licensure, "at which time the product, its therapeutic uses, and its manufacturing processes are fixed" because at that point there is a

"fully crystallized controversy." Pet. App. 21a.[22] But the court cited no basis in the text, structure, or legislative history of the statute for that belief, and there is every indication that Congress intended exactly the opposite.

A. Permitting Patent Litigation To Take Place Only When The Patent Controversy Is "Fully Crystallized" Is Inconsistent With The Statutory Structure And Would Be Nonsensical In Many Cases.

1. Respondents have argued that requiring that an applicant's commercial-marketing notice be provided only after FDA approval ensures that preliminary injunction motions are "based on the actual facts that matter" as "defined by the FDA license." Amgen Br. in Opp. 21. But Congress created a *pre-licensure* dispute-resolution process and built in substantial incentives for litigants to avail themselves of that process. *See Amgen, Inc. v. Apotex Inc.*, 827 F.3d 1052, 1059 (Fed. Cir. 2016); Pet. App. 71a-72a; *Biologics and Biosimilars Hearing* 9 (statement of Rep. Eshoo) (the early patent resolution process is intended to "ensure that all patent disputes involving a biosimilar are resolved before, and I emphasize before, the expiration of the data-exclusivity period"[23]). Congress also created "an artificial 'act of in-

---

[22] "Pet. App." refers to the petition appendix filed in No. 15-1039.

[23] Representative Eshoo referred to a 12-year "data-exclusivity period," but in context it is clear that she was referring to the 12-year *market* exclusivity period during which the FDA is prohibited from approving a biosimilar version of a particular biologic, not the 4-year data-exclusivity period during which a biosimilar application cannot even be filed. The bill Representative Eshoo discussed, H.R. 1548, contained 12- and 4-year peri-

fringement'" that permits "infringement suits based on a biosimilar application prior to FDA approval and prior to marketing" if an applicant fails to engage in the patent dance altogether. Pet. App. 6a (citing 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6)). If Congress had intended patent litigation to occur only after there was a "fully crystallized controversy" post-licensure, it would not have permitted—indeed, encouraged—infringement lawsuits to be filed shortly after an applicant submits a biosimilar application and long before approval.[24]

Furthermore, the Federal Circuit's concern with the waste of resources that could result from patent litigation over products that may never obtain FDA approval or that may be changed during the approval process, Pet. App. 21a, is simply unfounded. Both Hatch-Waxman and the BPCIA intentionally encourage applicants to resolve patent issues after an application is filed but before FDA approval—after the patent dispute is sufficiently "crystallized" for a

---

ods virtually identical to the ultimately-passed BPCIA. Pathway for Biosimilars Act, H.R. 1548, 11th Cong. § 101 (2009). *See generally* Erika Lietzan, *The Myths of Data Exclusivity*, 20 Lewis & Clark L. Rev. 91, 104 (2016) (noting the inconsistent usage of the terms "data exclusivity" and "market exclusivity").

[24] Amgen has argued that even if the controversy is sufficiently crystallized before licensure to be litigable generally, it is not until the FDA's licensure decision that the dispute is "fully crystallized" to permit a sponsor to seek preliminary injunctive relief. Amgen Supp. Br. 7-8. But injunctive relief is *already* available in pre-approval patent litigation under Hatch-Waxman and the BPCIA. *See* 35 U.S.C. § 271(e)(4)(B), (D). Congress would have had no reason to fear that a sponsor would be unable to establish the necessary elements for injunctive relief, such as irreparable harm to the sponsor itself, until the *biosimilar* has license in hand.

court to determine validity and infringement, yet before a patent owner could claim to have suffered any actual damages. That is why the BPCIA replicated what the Hatch-Waxman statute established more than thirty years ago—it created an artificial act of infringement so that the dispute could go to court and have a good chance of being resolved before a product is marketed.

2. Amgen itself argued before the district court that the extra six-month period would apply in *every* case. *See* note 9, *supra*. But post-licensure notice, followed by a mandatory additional 180-day stay on a biosimilar's launch, would be nonsensical in many instances. For instance, there may be no active patents left once a biosimilar application is filed. Indeed, many key patents that cover biologic drugs representing tens of billions of dollars in annual sales have expired or are set to expire within the next three years, and for many of these drugs no biosimilar applications have yet been filed. *See* Singh & Bagnato S332 ("In 2013, more than 70% of the spending on biologics was attributed to products with patents that have expired or will soon expire; 12 additional biologic product patents are scheduled to expire in the United States by 2020."). Or there may be no active patents remaining after Phase I litigation has taken place, if the biosimilar applicant has prevailed in that phase. Finally, in many instances patent protection for the biologic will expire by the end of the 12-year exclusivity period. Indeed, proponents justified the 12-year period as mimicking the patent protection historically enjoyed by branded

drugs after FDA approval.[25] In each of these situations, all that is left to do during the 180-day period is wait for the sake of waiting.

In other instances, prohibiting notice until after licensure would require years of needless delay, followed by an unnecessary scramble to resolve patent disputes between licensure and launch. Because an applicant's notice of commercial marketing triggers litigation on Phase II patents, permitting only *post*-licensure notice means that Phase II litigation could likewise occur only post-licensure if the applicant participates in the patent dance. As biosimilar development improves and biosimilar manufacturers begin filing applications sooner after the four-year data exclusivity period, then biosimilar companies that engage in the BPCIA's information-exchange and early-dispute-resolution process will likely resolve Phase I patent issues with five or more years left before market exclusivity ends. Under respondents' interpretation, the parties would then senselessly sit on their hands for half a decade or more before being able to initiate Phase II litigation—all while memories fade, evidence becomes stale, and time passes.

B. Precluding Notice and Phase II Litigation Before FDA Approval Would Deprive Biologics, Biosimilar Developers, And Investors Of Much-Needed Certainty.

Permitting notice (and thus Phase II litigation) only after a biosimilar applicant receives FDA approval would deprive biosimilars and biologics alike

---

[25] *See Biologics and Biosimilars Hearing* 8 (statement of Rep. Eshoo).

of much-needed certainty of patent validity and infringement issues. Certainty is vital to investor confidence in the patent world—particularly for pharmaceuticals. Knowing, as early as possible, whether a sponsor's patents are valid and infringed permits companies (both branded biologics as well as biosimilar developers) to make additional investments in biotechnology; it also "enable[s] the investor to determine whether or not to continue to pursue the commercial implementation of the new technology and will enable the investor to determine better where to invest in the future of that technology." Norman L. Balmer, *An Innovator's Prospective on Judicial Management in the United States*, 9 Fed. Cir. B.J. 615, 618 (2000).

The need for early patent certainty was not lost on Congress. Almost four decades ago, Congress enacted a patent reexamination process specifically aimed at reinforcing "investor confidence in the certainty of patent rights" by allowing the PTO to "settle validity disputes more quickly and less expensively than the often protracted litigation involved in such cases." *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed. Cir. 1985) (citation omitted). In passing that legislation, Congress recognized that efficient resolution of validity issues would "promote industrial innovation by assuring the kind of certainty about patent validity which is a necessary ingredient of sound investment decisions." H.R. Rep. No. 96-1307, at 4 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6463. The early patent resolution framework adopted in the BPCIA was similarly enacted "to expedite patent litigation concerning biosimilar products in order to maximize certainty, and diminish the risk that innovators will be unnecessarily deterred

from offering those products to the public." *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, __ F. Supp. 3d __, 2016 WL 5420566, at *6 (D. Mass. Sept. 26, 2016); *see also id.* at *7 ("[U]ncertainty relating to whether [a biosimilar] infringes a valid [patent covering a biologic] could affect decisions by potential investors in both Celltrion and Janssen."); FTC, *Follow-on Biologic Drug Competition* 50 (noting commentators' views that the "certainty" of "a pre-approval patent resolution process . . . would enhance their drug development activities," because "smaller companies . . . are unlikely to attract investment funds without certainty").

A biosimilar company wishing to avoid a cloud of uncertainty hanging over its biosimilar medicines for years under the respondents' rule would be left with two choices: include all patents in Phase I litigation, or skip the patent dance altogether, thus triggering a sponsor's right to file an immediate patent infringement action asserting all active patents. Either outcome would eviscerate the benefits of a multi-phase patent litigation framework that Congress deemed efficient and appropriate. Yet that is precisely what the respondents' interpretation would encourage.

III. RESPONDENTS' CONCERNS ABOUT "SURPRISE" BIOSIMILAR APPLICATIONS OR LAUNCHES DO NOT SUPPORT ENFORCING THE BPCIA'S PATENT DANCE PROVISIONS WITH AN EXTRA-TEXTUAL AUTOMATIC INJUNCTION OR ADDING SIX MONTHS OF EXTRA EXCLUSIVITY PERIOD FOR ALL BIOLOGICS.

Amgen has argued that its interpretation of the BPCIA is necessary to protect against a surprise FDA filing and product launch by biosimilar applicants. But the biosimilar pipeline is significantly transparent: there is no reason to suggest that a stealth filing or launch has ever been or could ever realistically be an actual concern, and it would be nonsensical to adopt a countertextual interpretation of the statute based on such imagined pragmatic worries. Moreover, the notion that a biosimilar manufacturer would file secretly and launch at risk when patent issues remain to be adjudicated, solely for the sake of taking its brand-name competitor by surprise, is extremely unrealistic: the entire reason for creating the artificial act of infringement is that enormous potential damages are a powerful disincentive to a stealth launch.

A. Respondents' Proposed Injunctive Remedy For A Biosimilar Developer's Failure To Engage In The Patent Dance Is Not Necessary To Protect Against A Secret Filing Or Surprise Launch.

As Sandoz explains (at 13-17), Congress provided biosimilar applicants with a choice about how to proceed with patent litigation: engage in the patent dance and enjoy the ability to control the phasing of

patent litigation, or decline to engage in the patent dance and be subject to an immediate patent-infringement action by the biologic sponsor. This choice makes eminent sense: there may be many instances in which a biologic has no more patent coverage by the time a biosimilar application is filed. In such instances, a biosimilar applicant would neither want nor need to provide its confidential business information to its competitor. Sandoz Br. 51.

Respondents have argued that although the BPCIA expressly sets forth a sponsor's recourse for an applicant's failure to engage in the patent dance after filing its biosimilar application (the right to file a patent-infringement action immediately), the Court should read into the statute an additional remedy—an automatic mandatory injunction requiring the applicant to engage in the patent dance. Respondents suggest that this extratextual remedy is necessary because (1) without the information exchange process, an applicant will "keep secret the fact that it has filed an [application]" and thus a sponsor will have no way to know that the right to file a declaratory judgment action was even triggered, Amgen Supp. Br. 1; and (2) without the information obtained from the patent dance, biologics sponsors will not have sufficient information to draft a patent-infringement complaint, *id.* at 13; PI Mot. Hrg. 13-14. These purported concerns are illusory and provide no reason to rewrite the statute to create a remedy that Congress did not provide or even contemplate.

First, there is no information deficit regarding the filing of a biosimilar application or, indeed, the biologic and biosimilar development pipeline in general. Pharmaceutical companies are subject to various

regulatory requirements and market pressures that make the development and approval pipelines for biologics and biosimilars both robust and transparent. Interested observers can easily track the development of biologic and biosimilar medicines through clinical trial announcements that companies are required to register publicly with the FDA, and through investor presentations and disclosures that publicly held companies must provide in compliance with SEC regulations.

For example, under the Food and Drug Administration Modernization Act of 1997,[26] the FDA is required to maintain a public information registry on all "federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions." Nat'l Institutes of Health, *History, Policies, and Laws*, ClinicalTrials.gov (Feb. 2, 2017), https://clinicaltrials.gov/ct2/about-site/history#CongressPassesLawFDAMA; *see also* 42 U.S.C. § 282(i). This registry allows the public to search for clinical studies according to a number of criteria, including the condition sought to be treated, the type of drug or "intervention" being studied, the sponsor or collaborator, and general search terms. For example, a search for "filgrastim," the drug in Amgen's Neupogen® product and Sandoz's Zarxio® product, produces results for various stages of clinical trials studying the drug, including the Phase III study of Sandoz's filgrastim product, which the site indicates was started in December 2011, received by the regis-

---

[26] Pub. L. No. 105-115, 111 Stat. 2296 (codified in scattered sections of 21 U.S.C. §§ 301-81).

try on January 13, 2012, and completed in June 2013.

Publicly held companies are required to provide their investors and the markets with regular updates on pipeline products, often including detailed information on expected development, regulatory approval timelines for such products, and potential litigation risks. Consequently, biosimilar applicants commonly make public announcements of critical development stages and of submissions to the FDA.[27]

In addition, both public and private companies regularly detail their pipelines in presentations to investors and potential investors. These presentations provide a similarly robust look into the biosimilar pipeline, with detailed information regarding clinical trial status and expected filing dates. *See, e.g.*, Sandoz, *Meet Novartis Management Investor Presentation* 24 (May 2016), https://www.novartis.com/sites/www.novartis.com/files/2016-06-meet-the-management-3-sandoz.pdf (past and anticipated biosimilar filings); Cadila Healthcare Limited, *Investor Presentation* 15 (May 2016), https://zyduscadila.com/wp-content/uploads/2016/05/InvestorPresentation-May2016.pdf (biosimilar pipeline, including development status).

---

[27] *E.g.*, Sandoz, Press Release, FDA accepts Sandoz application biosimilar filgrastim (Jul. 24, 2014), https://www.sandoz.com/news/media-releases/fda-accepts-sandoz-application-biosimilar-filgrastim; Coherus Biosciences, Press Release, Coherus Biosciences Announces Positive Topline 24-Week Treatment Phase Three Results For CHS-1420 (Humira® Biosimilar Candidate) In Patients With Psoriasis (Jan. 10, 2017), http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2236538.

Such announcements and presentations are important for public companies concerned about stock prices and providing transparent disclosures to investors, and for smaller or privately-owned companies that must obtain private financing to fund development activities. There is simply no incentive to keep such filings a secret, and the notion that an additional injunctive remedy for a biosimilar's failure to engage in the patent dance is necessary to protect a sponsor from the biosimilar's surprise filing is plainly inconsistent with the realities of the biopharmaceutical marketplace both today and when Congress passed the BPCIA.

Second, should biosimilar applicants decline to take part in the patent dance, biologic sponsors are fully capable of obtaining the information they need to pursue a patent-infringement action against applicants, just as Amgen did here. As the Federal Circuit correctly noted, all of the information that would be provided through the patent dance can be obtained through discovery in a patent-infringement action. Like anyone else preparing to file civil action, biologic sponsors must simply conduct a diligent and reasonable pre-filing investigation and include allegations that it has a good-faith belief will have evidentiary support after a reasonable opportunity for further discovery. Fed. R. Civ. P. 11.

Given the transparency of the biosimilar development pipeline based on federal regulatory requirements and the extensive information publicly available, obtaining sufficient information to draft a complaint is hardly an impossible task. Sponsors can search SEC disclosures, listen to investor and analyst calls, review conference presentations, and explore clinical trial information to determine

whether they have a good faith basis for alleging that one or more of their patents is infringed by an applicant. A sponsor can also request information about a biosimilar and its manufacturing process from an applicant through a "demand letter"; if the applicant refuses to provide such information, the sponsor can then file an infringement suit "on information and belief" in light of the applicant's failure to respond. *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1362-64 (Fed. Cir. 2000) (rejecting theory that patent plaintiffs must "obtain and set forth in their complaint facts showing infringement" when the plaintiff conducted a reasonable pre-filing inquiry, including a request for the defendant to disclose the method by which its product was made).

Respondents' further assertion that sponsors will have insufficient information about which claims to assert and thus "[v]alid claims will go unasserted," Supp. Br. 13, is likewise a false concern. "Infringement complaints are usually sparse and conclusory," merely alleging "that a defendant is directly or indirectly infringing a patent" and identifying the plaintiff's asserted patents. Fed. Judicial Ctr., *Patent Case Mgmt. Judicial Guide* 2-20 (2009). It is commonplace for a defendant to "not know which claims of the patents are being asserted against it" or even specifically "which of its products or processes are accused of infringing." *Id.* Nevertheless, "the patent holder is not required to do more" under our notice pleading standards. *Id.* It is equally commonplace for patent plaintiffs to assert initial patents and amend the complaint when new information is obtained in discovery. *See, e.g., 3Com Corp. v. D-Link Sys., Inc.*, No. C 03-2177 VRW, 2007 WL 949599, at *7 (N.D. Cal. Mar. 27, 2007) ("It is to be expected

that a patent holder may find other product designations that infringe as discovery progresses."); *SAP Aktiengesellschaft v. i2 Techs., Inc.*, 250 F.R.D. 472, 472 (N.D. Cal. 2008) (granting leave to amend to assert additional patent identified during discovery as infringed).

In short, biologic sponsors are not uniquely burdened in litigation simply because their competitors' confidential information may not be presented to them on a silver platter; instead, they are in the same position as every other patentee, and practically every other civil plaintiff, that litigates in federal court. There is simply no indication that Congress thought sponsors unable to bring patent lawsuits without the patent dance, and this nonexistent problem certainly cannot justify reading into the statute an injunctive remedy that artificially extends the 12-year monopoly.

Moreover, such a theory is inconsistent with both the text and overall structure of the statute. Congress made a biosimilar applicant's failure to provide its application to a biologic sponsor an artificial act of infringement that permits the sponsor to file a patent-infringement action immediately. 35 U.S.C. § 271(e)(2); 42 U.S.C. § 262(*l*)(9)(C). This would be a very odd remedy if Congress believed that sponsors lack sufficient information to bring a patent-infringement action absent the information provided during the patent dance. To the contrary, Congress recognized that in light of the realities of patent litigation, the right to bring an immediate patent-infringement action is an adequate remedy for an applicant's failure to engage in the patent dance.

B. Post-Licensure Notice Is Not Necessary To Protect Against A Stealth Launch.

Amgen has contended—and the Federal Circuit agreed—that a pre-licensure notice rule would encourage applicants to launch their products by surprise, with sponsors having no idea when commercial marketing will actually begin. Amgen Br. in Opp. 21; Pet. App. 21a. Amgen has also argued that without an automatic injunction for failing to provide notice, biosimilars will simply decline to give notice at all and take biologic patent holders and the courts by surprise by launching immediately upon FDA approval. Supp. Br. 1. But there is no reason to suggest that Congress thought a stealth launch has ever been or could ever be a concern.

First, as noted above, the biologic and biosimilar pipelines are robust and remarkably transparent. *See supra* pp. 28-30. Furthermore, absent a patent issue, biosimilar companies will generally want to launch as soon as they obtain approval so they can start recouping their investments immediately, and the FDA has been transparent about its approval timeline (within 10 months in 90% of cases[28]), leaving little question about a biosimilar's likely launch date. FDA approval itself is certainly not a stealthy matter; indeed, FDA issues a press release immediately upon approval of biosimilars, and the biosimilar applicants have done the same. *E.g.*, FDA, Press Release, FDA Approves First Biosimilar Product Zarxio, Mar. 6, 2015, http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm; Sandoz, Press Release, FDA approves Sandoz Erelzi™ to treat multiple inflammatory diseases

[28] FDA Biosimilar Authorization Performance Goals 3-4.

(Aug. 30, 2016), https://www.sandoz.com/news/media-releases/fda-approves-sandoz-erelzitm-treat-multiple-inflammatory-diseases.

Second, to the extent a surprise launch is ever realistic, it would occur when there are no more patents to be concerned about—and when there is therefore no reason to delay six more months following notice to a sponsor.[29] Under those conditions, a failure to tell the biologic sponsor about licensure of the biosimilar before launching would raise no legitimate concerns—the biologic sponsor no longer enjoys monopoly protection, and the biosimilar applicant has a right to sell its product once the FDA licenses it. As respondents themselves stated, the 180-day notice period is intended to "ensure an orderly litigation process," Supp. Br. 5; where there can be no conceivable litigation following notice, even a hypothetical risk of a stealth launch poses no practical concerns.

Given the practical realities of the biosimilar pipeline and biosimilar companies' economic interests in resolving patent litigation before launch, Congress simply would not have credited respondents' purported worry about the risk of a surprise launch. There is simply no reason to contort the statute to solve this fictional problem.

---

[29] The number of biologics not covered by patents is set to grow. *See* Blackstone & Fuhr 473 ("Between 2009 and 2019, $50 billion of the market value of biologics in the United States alone will lose patent protection.").

* * * * *

Congress did not extend biologic sponsors' monopoly for an additional six months past the 12 years the statute unambiguously provides. Nor did Congress silently authorize an injunctive remedy to combat a stealth launch that it had no reason to believe would ever occur.

CONCLUSION

The judgment of the court of appeals should be reversed with respect to the questions presented in Sandoz's petition and affirmed with respect to the question presented in Amgen's petition.

Respectfully submitted.

ELAINE HERRMANN BLAIS
ALEXANDRA LU
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210

WILLIAM M. JAY
Counsel of Record
JAIME A. SANTOS*
GOODWIN PROCTER LLP
901 New York Ave., N.W.
Washington, DC 20001
wjay@goodwinlaw.com
(202) 346-4000

February 17, 2017

Counsel for Amicus Curiae

* *Admitted to practice only in Massachusetts and California; practice supervised by William M. Jay.*